



CHILDREN'S MEDICAL SERVICES CARDIAC FACILITY REVIEW & RE-APPROVAL PROCESS

CARDIAC FACILITY REVIEW & RE-APPROVAL PROCESS

Children's Medical Services (CMS) Cardiac Facility Review and Re-approval Process is not a licensure process, but rather a quality assurance process to ensure that participating CMS Network cardiac facilities maintain established minimum standards deemed necessary for the provision of quality cardiac services to children with special health care needs.

The Children's Medical Services will perform annual reviews of CMS approved cardiac facilities as follows:

- All CMS cardiac facilities will undergo a full on-site review at least once every three (3) years.
- Interim cardiac data will be submitted by each facility and reviewed annually.
- Impromptu reviews may be scheduled on an as-needed basis for the following:
 1. Complaints regarding quality;
 2. A decline in cardiac volume numbers that brings the facility's numbers 5-10% below the current CMS cardiac volume standards;
 3. Increased incidence of morbidity and mortality;
 4. A change in physician members of the cardiac team.

Re-approval On-Site Review Process

The cardiac facility re-approval process involves completion of the CMS re-approval packet and an on-site facility review. The CMS cardiac facility re-approval process is not deemed complete until the facility on-site review has been performed. To assure timely re-approval of cardiac facility, the cardiac facility re-approval process must be completed within ninety (90) days of the on-site facility review.

A cardiac facility's approval date is the date of the Deputy Secretary's notification to the facility of their CMS approval.

Planning for On-Site Review

Four (4) months prior to the scheduled on-site review, the Deputy Secretary for Children's Medical Services provides the facility with notification of the upcoming review and a re-approval packet.

The re-approval packet that contains the following:

- CMS Cardiac Facility Re-approval Process Overview
- CMS Cardiac Facility Standards
- Re-Evaluation Form – CMS Cardiac Facility Standards
- Re-Evaluation Form – CMS Pediatric Non-Invasive Lab Facility
- Re-Evaluation Form – CMS Pediatric Cardiac Catheterization Facility
- Re-Evaluation Form – CMS Pediatric Cardiovascular Surgery Facility

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The facility should submit the completed evaluation forms listed above to:

Joseph J. Chiaro, M.D.
Deputy Secretary
Children's Medical Services
4052 Bald Cypress Way, Bin #A-06
Tallahassee, FL. 32399-1707

CMS Central Office (HCMS) staff reviews the evaluation forms to determine that all requested documentation has been received and that the facility meets current CMS cardiac volume standards. If additional information or clarification is required, a letter is sent to the facility requesting additional information within two (2) weeks of receipt of the evaluation forms.

The facility should submit the additional information within two (2) weeks of receipt of the request from HCMS.

- When it has been determined that all questions have been answered adequately and the facility **has maintained** current CMS volume requirements, a review team is assembled and the on-site review scheduled.
- When it has been determined that all questions have been answered adequately and the facility has had a decrease in cardiac procedure volume greater than a 10% below the current CMS cardiac volume standards, the review process terminates. The facility will be notified in writing of their **failure to consistently maintain** CMS cardiac volume standards and informed of their ability to reapply once the required volume standards have been achieved for a 12 month period.

The cardiac facility site visit review team consists of the following members:

- **HCMS Staff**
 - ☐ HCMS Nursing Consultant for Cardiac Program
- **Physician Consultants**
 - ☐ CMS approved pediatric cardiologist
 - ☐ CMS approved cardiac surgeon

The Deputy Secretary for CMS or designee in consultation with the CMS Statewide Cardiac Consultant will recommend the cardiologist and cardiac surgeon for the review.

Following the Deputy Secretary's recommendations, HCMS will provide the selected physicians a written request to participate, which asks them to respond to the invitation within two (2) weeks of receipt.

Upon receipt of acceptance to participate on the review team, the on-site review will be scheduled within 45 days of the physician's acceptance to participate.

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Two (2) weeks prior to the scheduled site visit, the reviewing physicians and all team members are provided with the following information:

- Date and Time of Site Review
- Facility Name, Location, and Telephone Number
- Directions to the Facility / Meeting Room Location
- HCMS Contact Person
- Site Visit Agenda
- Copies of Completed Evaluation Forms
- Copies of Review Tools and Report Format

On-Site Review

The cardiac facility should plan for the following individuals/disciplines to be available during the site visit:

- Pediatric Cardiologists
- Pediatric Cardiovascular Surgeon

The following activities will occur during the on-site review:

- Entrance meeting for introductions and for the cardiac facility staff to provide an overview of the cardiac program.
- Review team will tour the surgical suite, pediatric intensive care unit, and outpatient surgical area, as applicable.
- Requested patient records will be reviewed.

Post Review Activities

Within two (2) weeks following the site visit, the CMS Statewide Cardiac Consultant should submit a report of findings and program recommendations to the Deputy Secretary for Children's Medical Services.

Within four (4) weeks following the receipt of the written report from the statewide consultant a meeting of the CMS Cardiac Subcommittee will be held to discuss and review findings and recommendations. The meeting may occur via conference call or face-to-face.

The Deputy Secretary will notify the facility in writing of their status as a CMS Cardiac facility within two (2) weeks following the Subcommittee meeting.

If re-approval is **not** recommended, the Deputy Secretary will provide the facility with recommendations for changes necessary to achieve CMS Cardiac facility re-approval.

A copy of the re-approval or disapproval letter from the Deputy Secretary for CMS will be provided to the CMS Statewide Cardiac Consultant, the local CMS Regional Medical Director, Regional Nursing Director and Program Administrator.

Annual Interim Review Process

Annual surgical data from each facility will be received via the annual Society for Thoracic Surgery (STS) Regional Report each fall. If the facility fails to submit the requested data by the deadline, the Deputy Secretary for CMS will notify the facility in writing that failure to comply with the data request within 30 days will result in loss of CMS cardiac facility approval.

HCMS headquarters staff reviews the data reports to determine that all requested information has been received and that the facility meets current CMS cardiac volume standards. If additional information or clarification is required, a letter is sent to the facility requesting additional information within two (2) weeks of receipt of the data reports.

The facility should submit the additional information within two (2) weeks of receipt of the request from HCMS.

- When it has been determined that all data has been received and the facility **has maintained** current CMS volume requirements, the facility will be notified in writing of their continued CMS cardiac facility approval status.
- When it has been determined that all data has been received and the facility has had a cardiac procedure volume decrease of less than 10% below the current CMS cardiac volume standards, an impromptu on-site facility review will be scheduled. The facility will be notified in writing of the impromptu on-site review.
- When it has been determined that all data has been received and the facility has had a cardiac procedure volume decrease greater than 10% below the current CMS cardiac volume standards, the facility will be notified in writing of their loss of CMS cardiac facility approval status for **failure to consistently maintain** CMS cardiac volume standards. The facility will also be informed of their ability to reapply once the required volume standards have been achieved for a 12-month period.

Within four (4) weeks following the receipt of the data reports, a meeting will be held with the CMS Cardiac Subcommittee to discuss and review findings and recommendations. The meeting may occur via conference call or face-to-face.

The Deputy Secretary will notify the facility in writing of their continued status as a CMS Cardiac facility within two (2) week following the Subcommittee meeting.

If re-approval is **not** recommended, the Deputy Secretary will provide the facility with recommendations for changes necessary to achieve re-approval.

A copy of the re-approval or disapproval letter from the Deputy Secretary for CMS will be provided to the CMS Statewide Cardiac Consultant, the Cardiac Subcommittee of the CMS Advisory Council members, the local CMS Regional Medical Director, Regional Nursing Director and Program Administrator.

The CMS Network Advisory Council will be advised of cardiac facility status during scheduled meeting of the council.

Impromptu On-site Review Process

Impromptu reviews of CMS approved cardiac facilities may be performed based upon concerns or issues relating to significant decrease in volume standard numbers, increased incidents of morbidity and mortality, or patient complaints regarding quality

Impromptu on-site facility review process is identical to the re-approval on-site review process.